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PATREA L. PABST
PABST PATENT GROUP LLP
400 COLONY SQUARE, SUITE 1200
1201 PEACHTREE STREET
ATLANTA, GA 30361

EXAMINER	
FUBARA, BLESSING M	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/053,929
Filing Date: January 22, 2002
Appellant(s): STRAUB ET AL.

Rivka D. Monheit
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 07/09/07 appealing from the Office action mailed 12/08/2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings, which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

Unger, van C. "Solid Matrix Therapeutic Compositions" United States Patent Application Publication, Pub. No. US 2001/0018072 (Aug 30, 2001).

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16-21 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger (US 2001/0018072).

Unger discloses solid porous matrix that contains bioactive agent, surfactant and solvent (abstract) and a bicarbonate (paragraph 167); the solvent can be organic or aqueous (paragraph 74); the drying methods include, lyophilizing, spray drying, and the combination thereof (paragraphs 14 and 76); some of the bioactive agents that can be prepared according to Unger are anti-neoplastic agents, methotrexate, adriamycin (paragraph 135). Surfactant is an excipient. Ammonium carbonate is a volatile pore forming salt. The instant method comprises steps a-d and the steps a-c read on mixing the bioactive agent, the volatile pore forming agent and excipient and removes the solvent by lyophilizing or spray drying. The lyophilizing step in Unger is a process of removing solvent and the pore forming agent as is claim 16 d. Unger's method steps may not specifically disclose the claimed method steps according to the steps from 16 a-d. For example, in example 1, Unger places dexamethasone in PEG and that mixture is then dissolved in methanol and rotary evaporated under vacuum. There is no demonstration that the recited method steps, in the exact order provides unexpected results to the porous matrix and also that the specific method

steps are known in the art for the production of powder formulation (for example, column 2, lines 49-51; column 3, line 30 and column 9, line 41, of US 5,976,574 issued to Gordon, Nov. 02, 1999 a teaching reference discloses preparing powder by dissolving a drug in the solvent, adding excipient to the solution and then spray drying). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a porous matrix according to Unger. One having ordinary skill in the art would have been motivated to use the known steps of preparing the powder with the expectation of forming a porous matrix. In the absence of showing factual evidence, the recited steps of making the porous matrix does not patentably distinguish the claimed invention over the prior art.

(10) Response to Argument

a) Appellant says that Unger does not disclose or suggest elements (b), (c), and (d) of claims 16, but while Unger may not have disclosed the steps in the order of (b), (c), and (d), the elements of combining a volatile solid pore forming agent with the drug solution to form an emulsion, which is step (b), incorporating at least one excipient into the emulsion, which is (c), removing the volatile solvent and the pore forming agent from the emulsion, which is (c) are present in Unger because Unger discloses a method of making a porous matrix by combining **surfactant**, **bioactive agent** or **therapeutic agent**, **together with a solvent** (see paragraph [0014], the abstract and optionally gas or gaseous precursor (see paragraph [0013]), and the porous matrix is formed either by lyophilizing or spray drying (paragraphs [0014] and [0076]). In one of the embodiments, the gaseous precursor is lithium bicarbonate, sodium bicarbonate, potassium bicarbonate, magnesium carbonate, calcium carbonate, magnesium bicarbonate, ammonium carbonate, ammonium bicarbonate, ammonium sesquecarbonate, or sodium sesquecarbonate (see

paragraph [0167]) and appealed claim 21 identifies ammonium carbonate as a volatile solid pore forming agent.

b) Appellant says that the gas or gaseous precursors are not pore forming, but Unger specifically states that in one of the embodiments, the gaseous precursors are lithium bicarbonate, sodium bicarbonate, potassium bicarbonate, magnesium carbonate, calcium carbonate, magnesium bicarbonate, ammonium carbonate, ammonium bicarbonate, ammonium sesquecarbonate, or sodium sesquecarbonate (see paragraph [0167]). It is also brought to appellant's attention that claim 21 identifies ammonium carbonate as a volatile solid pore forming agent, and the ammonium carbonate is one of the gaseous precursors of Unger as stated above. A chemical compound and its properties are inseparable so that the ammonium carbonate of Unger would inherently have pore forming properties.

c) Appellant states that Unger refers to the gases and gaseous precursors as solvents and solvents are **generally** liquids while the pore forming agents of the claimed invention are volatile solids. However, a solvent is the constituent of the solution that predominates in the solution. Thus in a solid-in-solid solution, one solid that is the predominate constituent of the solution is the solvent. Thus, solvents are not always liquids. Furthermore, Unger refers to an embodiment in which the gaseous precursors are lithium bicarbonate, sodium bicarbonate, potassium bicarbonate, magnesium carbonate, calcium carbonate, magnesium bicarbonate, ammonium carbonate, ammonium bicarbonate, ammonium sesquecarbonate and these compounds are solids just as ammonium carbonate is defined in claim 21 as a volatile solid.

d) "Bicarbonate of PEG" is a typographical error in the Advisory. The examiner intended to say bicarbonate or PEG and the appellant is correct that Unger does not disclose "bicarbonate of PEG."

e) Regarding methylene chloride, it is noted that, the use of methylene chloride is another embodiment in which Unger forms porous matrix. Unger discloses other embodiments that use ammonium bicarbonate as gaseous precursor.

f) Regarding Example 1, examiner agrees with appellant that Example 1 does not meet the limitations of claim 16 and this is why the rejection over Unger is not one of anticipation but one in which the method steps are rendered obvious my the method of Unger, whose goal is to produce porous matrix.

g) Appellant states that volatile pore forming agents are subset of pore forming agents and that sodium chloride are not volatile because they do not evaporate at relatively low temperatures and pressures. While this may be true and supported by the MSDS data on these substances, it is noted that Unger discloses ammonium carbonate as a gaseous precursor, which is one of the volatile salts and pore forming agent according to instant claims 20 and 21. It is further noted that Unger has not defined sodium chloride as a gaseous precursor (see paragraph [0167].

h) Appellant states that Unger does not disclose compositions containing an excipient that enhances the dissolution rate of the drug, stabilizes the drug in an amorphous form by preventing crystallization, or stabilizes the drug in crystalline form by inhibiting crystal growth. But, it is noted that enhancing the dissolution rate of the drug, stabilizing the drug in an amorphous form by preventing crystallization, or stabilizing the drug in crystalline form by inhibiting crystal growth are all derived from the function and properties of the excipient and the surfactant of Unger meets the excipient of claim 16. Furthermore, Unger in paragraph [0019] refers to "surfactant" or "surface active agent" as substance that alters energy relationship at interfaces, such as, for example, synthetic organic compounds displaying surface activity, including, inter alia, **wetting agents**, detergents, penetrants, spreaders, dispersing agents, and **foaming agents**, hydrophobic

compounds, such as include phospholipids, oils, and fluorosurfactants." Claim 18 defines wetting agents and polymers as excipients. Therefore, Unger's composition containing wetting agent contains excipient and would also inherently perform the recited function, which stems from the inherent properties of the excipient.

i) Appellant states that the Unger does not suggest that microparticles formed by the process of Unger have the properties specified by claim 16, but since the product formed by Unger and the claimed method have the same constituents, it follows that the composition of the product formed by the claimed method and that formed by the Unger method are the same, and same compositions must have the same properties and "products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present." See MPEP 2112.01 [R-3] II.

j) Appellant extensively discussed KSR and stated that the courts affirmed the Graham v. John Deere TSM test and as such the analysis in the rejection of the claims should have used the TSM test. However, it is noted that while the court affirmed the TSM test, the court also said that the TSM test is not the only criteria that should be used in determining whether a claimed invention is rendered obvious by teaching of the prior art. In the instant case, it was considered obvious to use known steps of preparing a powder with the expectation of forming porous matrix.

k) Appellant states that secondary considerations of the claimed invention has to do with formulating pharmaceutical compositions containing drugs having low solubility so that in consideration of the Graham analysis, the person of ordinary skill would not have been motivated to modify Unger. This is not found persuasive because, i) the generic claim 16 does not refer to low solubility drug, ii)Unger is concerned with formulating drugs such as antiviral drugs,

antibiotics, anti-inflammatories (paragraph 135, right column of page 16), all of which meet the requirement of claim 34. If the classes of drugs recited in claim 34 are low solubility, then, at least the classes of drugs mentioned above and contemplated for formulation by Unger are also low solubility drugs, iii) the formulation of Unger is porous just as the claimed product formed by the claimed method, and Unger's formulation contains same excipients as that prepared by the claimed method. Therefore, the person of ordinary skill in the art would be led to formulate the low solubility drugs of Unger by the methods recognized as part of the ordinary capabilities of one skilled in the art. The selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results; the selection of any order of mixing ingredients is prima facie obvious in the absence of new or unexpected results.

Therefore, Unger renders claims 16-21 and 34 obvious.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

BF Mahbara

Conferees:

Hartley, Michael

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER

Wax, Robert

ROBERT A. WAX
PRIMARY EXAMINER
TC/AS Appeals Specialist